NOV 20 2012

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Charles W. Kolifrath
(978) 421-9786

Date Summary Prepared:

June 4, 2012

Device:

RescueNet 12-Lead

Classification:

System, Network and Communication, Physiological Monitors. Product Code MSX. Device Class II.
Software, Transmission and Storage, Patient Data. Product code: NSX. Device Class: Not Classified.

Description:

The proposed RescueNet 12-Lead is a software-only product.

RescueNet 12-Lead is a web-based management system that uses a web browser to provide quick, easy access to 12-Lead records sent from ZOLL defibrillators, and physiological and patient data from other patient care systems. With RescueNet 12-Lead, users can view, distribute, close, add notes, and print 12-Lead records, and can search for Inbox and/or closed 12-Lead records, and run reports.

Indications For Use:

The RescueNet 12-Lead (RN12L) System is a data transmission and reception system that provides the capability to receive 12-Lead ECG reports, other physiological data, patient demographic, and EMS agency information from authorized monitor/defibrillators and other patient care systems and route it to a receiving destination at a remote location for display on an Internet Browser. Data is received from the field and can be used for diagnosis, disposition, and

therapy decisions by qualified medical personnel.

Substantial Equivalence:

The features and functions of the proposed RescueNet 12-Lead are substantially equivalent to the corresponding features and functions of the Physio-Control LIFENET System (K102757, cleared for use on 11/5/2010).

Comparison of Technological Characteristics

RescueNet 12-Lead features and functions are similar to the corresponding features and functions of the indicated predicate device. Both RescueNet 12-Lead and the indicated predicate device are software-only products intended for the collection and transmission of data from other medical devices. No new issues of safety or effectiveness are raised by this premarket notification.

Performance Testing:

Extensive performance testing ensures that RescueNet 12-Lead performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications.

Conclusion

Performance testing of RescueNet 12-Lead demonstrates that its features and functions are substantially equivalent to the corresponding features and functions of the indicated commercially distributed predicate device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 20 2012

ZOLL Medical Corporation
c/o: Chuck Kolifrath
Regulatory Affairs Manager
269 Mill Road
Chelmsford, MA 01824-4105

Re: K121865
Trade Name: RescueNet 12-Lead
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor including cardiotachometer and rate alarm
Regulatory Class: II (two)
Product Code: MSX
Dated: November 9, 2012
Received: November 13, 2012

Dear Mr. Kolifrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **RescueNet 12-Lead**

Indications For Use:

The RescueNet 12-Lead (RN12L) System is a data transmission and reception system that provides the capability to receive 12-Lead ECG reports, other physiological data, patient demographic, and EMS agency information from authorized monitor/defibrillators and other patient care systems and route it to a receiving destination at a remote location for display on an Internet Browser. Data is received from the field and can be used for diagnosis, disposition, and therapy decisions by qualified medical personnel.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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